UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

WAYNE COUNTY COMMISSION,

Plaintiff,

v.

RITE AID OF MARYLAND, INC. *dba* Rite Aid Mid-Atlantic Customer Support Center, Inc.,

CVS INDIANA, L.L.C.,

McKESSON CORPORATION,

CARDINAL HEALTH, INC.,

SAJ DISTRIBUTORS,

WAL-MART STORES EAST, LP *dba* Wal-Mart Pharmacy Warehouse #46,

WAL-MART STORES EAST, LP *dba* Wal-Mart Pharmacy Warehouse,

AMERISOURCEBERGEN DRUG CORPORATION, and

TOP RX, LLC,

Defendants.

CIVIL ACTION NO. 3:17-cv-01962

COMPLAINT

Plaintiff, WAYNE COUNTY COMMISSION, brings this civil action to eliminate the hazard to public health and safety and to abate the public nuisance caused by the opioid epidemic in Wayne County, West Virginia. In support of its effort, Plaintiff alleges as follows:

1. Plaintiff, WAYNE COUNTY COMMISSION, is a public corporation which may sue and plead in its own name. W. Va. Code § 7-1-1(a) [2008]. Plaintiff is a "political subdivision" and is neither an agency nor an agent of the State of West Virginia. W. Va. Code § 29-12A-3(c) [1986]; W. Va. Code § 14-2-3 [1967]; *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).

2. Defendant, RITE AID OF MARYLAND, INC., is registered with the West Virginia Secretary of State as a Maryland corporation with its principal office located in Camp Hill, Pennsylvania, doing business as RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER, INC.

3. Defendant, CVS INDIANA, L.L.C., is registered with the West Virginia Secretary of State as an Indiana limited liability company with its principal office located in Woonsocket, Rhode Island.

4. Defendant, McKESSON CORPORATION, is registered with the West Virginia Secretary of State as a Delaware corporation with its principal office located in San Francisco, California.

5. Defendant, CARDINAL HEALTH, INC., is an Ohio corporation with its principal office located in Dublin, Ohio.

6. Defendant, SAJ DISTRIBUTORS, is an Arkansas corporation with its principal office located in Pine Bluff, Arkansas.

7. Defendant, WAL-MART STORES EAST, LP, is registered with the West Virginia Secretary of State as a Delaware limited partnership with its principal office located in

Bentonville, Arkansas, doing business as WAL-MART PHARMACY WAREHOUSE #46 and/or WAL-MART PHARMACY WAREHOUSE.

8. Defendant, AMERISOURCEBERGEN DRUG CORPORATION, is registered with the West Virginia Secretary of State as a Delaware corporation with its principal office located in Chesterbrook, Pennsylvania.

9. Defendant, TOP RX, LLC, is a Delaware limited liability company with its principal office located in Bartlett, Tennessee.

10. Defendants, collectively referred to herein sometimes as "Defendant Wholesale Distributors," are in the chain of distribution of prescription opiates, namely hydrocodone and oxycodone, and known to have sold over **8 million doses** to pharmacies in Wayne County, West Virginia, between 2007 and 2012.

ENOUGH FACTS TO STATE A CLAIM TO RELIEF THAT IS PLAUSIBLE ON ITS FACE

11. Defendant Wholesale Distributors owe a ***duty*** under federal law, 21 U.S.C. § 823, 21 CFR 1301.74, and West Virginia state law, 15 CSR 2.4, to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from Wayne County, West Virginia.

12. The ***foreseeable*** harm from a breach of this duty is the diversion of prescription opiates for nonmedical purposes.

13. Defendant Wholesale Distributors repeatedly and purposefully ***breached*** its duties under federal and state law which is a direct and proximate ***cause*** of the diversion of millions of prescription opiates for nonmedical purposes in Wayne County, West Virginia.

14. The unlawful diversion of prescription opiates is a direct and proximate ***cause*** of prescription opiate abuse, addiction, morbidity and mortality in Wayne County, West Virginia.

15. The unlawful diversion of prescription opiates is a direct and proximate ***cause*** of the opioid epidemic currently plaguing Wayne County, West Virginia.

16. The opioid epidemic in Wayne County, West Virginia, remains an immediate ***hazard to public health and safety***.

17. The opioid epidemic in Wayne County, West Virginia, is a temporary ***public nuisance*** and remains unabated.

18. The WAYNE COUNTY COMMISSION has the ***standing*** to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-3kk [2002].

19. The WAYNE COUNTY COMMISSION passed a *Resolution* declaring the unlawful distribution of prescription pain pills a public nuisance and brings this civil action against the Defendant Wholesale Distributors seeking ***damages*** necessary to eliminate the hazard to public health and safety as well as abate, or cause to be abated, the public nuisance. *See* Wayne County Resolution attached hereto as Exhibit 1.

DUTY

20. The Controlled Substances Act ("CSA") and its implementing regulations create restrictions on the distribution of controlled substances. *See* 21 U.S.C. §§ 801–971 (2006); 21 C.F.R. §§ 1300–1321 (2009).

21. The main objectives of the CSA are to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. The CSA categorizes all controlled substances into five schedules. The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein. The CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping. *Gonzales v. Raich*, 545 U.S. 1, 12–14 (2005) (internal citations omitted).

22. The CSA authorizes the DEA to establish a registration program for manufacturers, distributors, and dispensers of controlled substances designed to prevent the diversion of legally produced controlled substances into the illicit market. H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970); *see* 21 U.S.C. § 801(2); 21 U.S.C. §§ 821-824, 827, 880. Any entity that seeks to become involved in the production or chain of

distribution of controlled substances must first register with the DEA. 21 U.S.C. § 822; 21 C.F.R. § 1301.11.

23. The CSA provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain ***illegal***. 1970 U.S.C.C.A.N. 4566, 4569 (emphasis added).

24. "Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *United States v. Moore*, 423 U.S. 122, 135 (1975).

25. Distributors of Schedule II drugs—controlled substances with a "high potential for abuse," 21 U.S.C. §§ 812(b), 812(2)(A)-(C)—must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels," *id.* § 823(b)(1). In addition, distributors that supply controlled substances to pharmacies must "design and operate a system to disclose to the [distributor] suspicious orders of controlled substances" and, in turn, disclose those suspicious orders to the DEA. 21 C.F.R. § 1301.74(b). "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206–07 (D.D.C. 2012).

26. The CSA is designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a "closed" system of drug distribution for legitimate handlers of such drugs. **Such a closed system is**

intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. 1970 U.S.C.C.A.N. 4566, 4571-72.

27. Defendant Wholesale Distributors are "one of the key components of the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people." *See* U.S. Department of Justice, Drug Enforcement Administration, letter to Cardinal Health dated September 27, 2006, attached hereto as Exhibit 2 ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.").

28. "Suspicious orders" include orders of an unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the wholesale distributor's

responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry. *See* U.S. Department of Justice, Drug Enforcement Administration, letter to Cardinal Health dated December 27, 2007, attached hereto as Exhibit 3 ("This letter is being sent to every entity in the United States registered with the Drug Enforcement Agency (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).")

29. The closed system of the CSA is specifically designed with checks and balances between registrants to ensure that controlled substances are not diverted from this closed system. *See* Declaration of Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Agency, United States Department of Justice, ¶8, *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 2012 WL 11747342 (US Dist. DC 2012) attached hereto as Exhibit 4.

30. The CSA seeks, through appropriate regulation of the manufacture and distribution of drugs, to reduce the availability of drugs subject to abuse except through legitimate channels of trade and for legitimate uses. 1970 U.S.C.C.A.N. 4566, 4574.

31. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations carefully define each participant's role and

responsibilities. *See* Brief for Healthcare Distribution Management Association[1] (HDMA) and National Association of Chain Drug Stores[2] (NACDS) as Amici Curiae in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, 2016 WL 1321983, *10 (C.A.D.C.) (April 4, 2016) attached hereto as Exhibit 5.

32. **Federal law imposes a duty upon the Defendant Wholesale Distributors to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.** 21 U.S.C.A. § 823(b)(1).

33. **Federal law imposes a duty upon the Defendant Wholesale Distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."** 21 CFR 1301.74(b).

34. Federal law imposes a duty upon the Defendant Wholesale Distributors to comply with applicable State and local law. 21 U.S.C.A. § 823(b)(2).

35. The West Virginia Legislature enacted the West Virginia WHOLESALE DRUG DISTRIBUTION LICENSING ACT OF 1991, W. Va. Code § 60A-8-1 *et seq.* [1991], to protect the

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[1] The Healthcare Distribution Management Association (HDMA or HMA) is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation, and H. D. Smith Wholesale Drug Co.

[2] The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart.

health, safety, and general welfare of residents of this state and authorized that the board of pharmacy shall promulgate rules to carry out its purpose.

36. **West Virginia state law imposes a duty upon the Defendant Wholesale Distributors to provide effective controls and procedures to guard against theft and diversion of controlled substances.** 15 CSR 2-4.2.1.

37. **West Virginia state law imposes a duty upon the Defendant Wholesale Distributors to design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the West Virginia Board of Pharmacy of suspicious orders when discovered. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.** 15 CSR 2-4.4.

38. **Defendant Wholesale Distributors have a duty to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific and industrial channels.** *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

39. These duties are well known to the Defendant Wholesale Distributors. "DEA regulations that have been in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)." *See* Brief for HDMA and NACDS, *4, *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, Exhibit 5.

40. The DEA has provided briefings to each of the Defendant Wholesale Distributors and conducted a variety of conferences regarding their duties under federal law.

41. The DEA sent a letter to each of the Defendant Wholesale Distributors on September 26, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm." *See* Exhibit 2.

42. The DEA sent a second letter to each of the Defendant Wholesale Distributors on December 27, 2007. This letter reminds the Defendant Wholesale Distributors of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.
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> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it

> deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the pattern throughout the segment of the regulated industry.
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> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

See Exhibit 3. Finally, the DEA letter references the final order issued in *Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007) which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."

43. Defendant Wholesale Distributors "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society." *See* Brief for HDMA and NACDS, *4, *Masters*

Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin., Exhibit 5; Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, 2012 WL 1637016, *2 (C.A.D.C.) (May 9, 2012) attached hereto as Exhibit 6.

44. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.

45. Each of the Defendant Wholesale Distributors is registered with the DEA as distributors in the chain of distribution of Schedule II controlled substances and assumed the duties imposed under the CSA.

46. Each of the Defendant Wholesale Distributors is a "registrant" as a distributor in the chain of distribution of Schedule II controlled substances and assumed the security requirement duties imposed under the regulations adopted by the West Virginia Board of Pharmacy.

47. Each of the Defendant Wholesale Distributors sold prescription opiates, including hydrocodone and/or oxycodone, to retailers in Wayne County, West Virginia.

48. Hydrocodone and oxycodone are Schedule II controlled substances under the CSA which have a currently accepted medical use but have a high potential for abuse, and its abuse may lead to severe psychological or physical dependence. *United States v. Bell*, 667 F.3d 431, 442 (4th Cir. 2011); 21 U.S.C. § 812(b)(2); 21 C.F.R. § 1308.12(b)(1)(xiii).

49. ***Hydrocodone*** is the most frequently prescribed opioid in the United States and is associated with more drug abuse and diversion than any other licit or illicit opioid. Its street names include Hydro, Norco, and Vikes. It is an orally active agent most frequently prescribed for the treatment of moderate to moderately severe pain. There are numerous brand and generic hydrocodone products marketed in the United States. All are combination products. The most frequently prescribed combination is hydrocodone and acetaminophen (for example, Vicodin®, Lorcet®, and Lortab®). Other examples of combination products include those containing aspirin (Lortab ASA®), ibuprofen (Vicoprofen®) and antihistamines (Hycomine®). Most often these drugs are abused by oral rather than intravenous administration. *See* DEA Drug Fact Sheet: Hydrocodone, https://www.dea.gov/druginfo/drug_data_sheets/Hydrocodone.pdf.

50. ***Oxycodone*** is a semi-synthetic narcotic analgesic and historically has been a popular drug of abuse among the narcotic abusing population. Its street names include Hillbilly Heroin, Kicker, OC, Ox, Oxy, Perc, and Roxy. Oxycodone is marketed alone as OxyContin® in 10, 20, 40 and 80 mg. controlled-release tablets and other immediate-release capsules like 5 mg. OxyIR®. It is also marketed in combination products with aspirin such as Percodan® or acetaminophen such as Roxicet®. Oxycodone is abused orally or intravenously. The tablets are

crushed and sniffed or dissolved in water and injected. Others heat a tablet that has been placed on a piece of foil then inhale the vapors. *See* DEA Drug Fact Sheet: Oxycodone, https://www.dea.gov/druginfo/drug_data_sheets/Oxycodone.pdf.

51. Hydrocodone and oxycodone are opiate pain-relieving medications having an addiction-forming or addiction-sustaining liability similar to morphine. *United States v. Bell*, 667 F.3d 431, 442 (4th Cir. 2011) ; 21 U.S.C.A. § 802(18).

52. Prescription opiate drugs provide serious addiction or abuse problems. 1970 U.S.C.C.A.N. 4566, 4569.

53. Defendant Wholesale Distributors owe a duty to monitor suspicious orders of prescription opiates originating from Wayne County, West Virginia.

54. Defendant Wholesale Distributors owe a duty to detect suspicious orders of prescription opiates originating from Wayne County, West Virginia.

55. Defendant Wholesale Distributors owe a duty to investigate suspicious orders of prescription opiates originating from Wayne County, West Virginia. *See Masters Pharmaceuticals, Inc.; Decision and Order*, 80 FR 55418-01, 55477 (September 15, 2015).

56. Defendant Wholesale Distributors owe a duty to refuse suspicious orders of prescription opiates originating from Wayne County, West Virginia. *See State of W. Virginia Morrisey v. McKesson Corp.*, 2017 WL 357307 (S.D.W. Va. Jan. 24, 2017).

57. Defendant Wholesale Distributors owe a duty to report suspicious orders of prescription opiates originating from Wayne County, West Virginia.

58. Defendant Wholesale Distributors owe a duty to prevent the diversion of prescription opiates into illicit markets in Wayne County, West Virginia.

59. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opiates for nonmedical purposes.

60. The foreseeable harm resulting from the diversion of prescription opiates for nonmedical purposes is abuse, addiction, morbidity and mortality in Wayne County and the damages caused thereby.

BREACH

61. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system created by the CSA collapses. *See* Declaration of Joseph Rannazzisi, ¶10, Exhibit 4.

62. Defendant Wholesale Distributors are required under the CSA to maintain, on a current basis, a complete and accurate record of each prescription opioid received, sold, delivered, or otherwise disposed of. 21 U.S.C.A. § 827(a)(3).

63. Defendant Wholesale Distributors report the sale of all prescription opiates, including those to pharmacies in Wayne County, West Virginia, to the Automation of Reports and Consolidated Orders System (ARCOS) database. *United States v. Four Hundred Sixty Three Thousand Four Hundred Ninety Seven Dollars & Seventy Two Cents ($463,497.72) in U.S. Currency From Best Bank Account*, 779 F. Supp. 2d 696, 709 (E.D. Mich. 2011).

64. The DEA has disclosed to the West Virginia Attorney General certain data from the ARCOS database relating to the sale of hydrocodone and oxycodone doses to retailers in West Virginia between 2007 and 2012. This information has become public knowledge as reported by the Charleston Gazette and reveals that drug wholesalers sold West Virginia pharmacies 780 million hydrocodone and oxycodone pills during this timeframe. *See* Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*, CHARLESTON GAZETTE (December 17, 2016). The records also disclose the number of prescription opiates sold to each of the 55 counties in West Virginia between 2007 and 2012. The data does not disclose the distributions per pharmacy nor the monthly shipments. Nonetheless, the data reveals that the Defendant Wholesale Distributors sold some **8 million doses** of hydrocodone and oxycodone to Wayne County pharmacies between 2007 and 2012. Specifically, the data reveals as follows:

	Wayne County 2007 - 2012 (Top Wholesalers)								
	WHOLESALER	**COUNTY**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**Grand Total**
1	RITE AID MID-ATLANTIC	WAYNE	253,100	270,500	263,200	259,050	226,900	204,370	1,477,120
2	CVS INDIANA	WAYNE	230,000	256,200	305,700	248,700	261,500	133,200	1,435,300
3	MCKESSON CORPORATION	WAYNE	208,000	225,800	237,840	187,130	211,460	191,290	1,261,520
4	CARDINAL HEALTH	WAYNE	53,600	98,800	60,300	229,840	246,230	326,370	1,015,140
5	SAJ DISTRIBUTORS	WAYNE	225,500	195,000	195,500	170,000	113,500	68,000	967,500
6	WAL-MART PHCY WAREHOUSE #46	WAYNE	21,400	171,800	172,600	187,400	180,200	171,900	905,300
7	AMERISOURCEBERGEN DRUG CORP	WAYNE	221,900	222,700	219,100	0	0	0	663,700
8	TOP RX, INC.	WAYNE	108,200	80,600	76,700	76,500	60,500	32,500	435,000
9	WAL-MART PHARMACY WAREHOUSE	WAYNE	129,600	0	800	0	0	0	130,400
	TOTALS		**1,451,300**	**1,521,400**	**1,531,740**	**1,358,620**	**1,300,290**	**1,127,630**	**8,290,980**

65. Defendant, RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER, INC., sold more than 1.4 million doses to pharmacies in Wayne County between 2007 and 2012.

66. Defendant, CVS INDIANA, L.L.C., sold more than 1.4 million doses to pharmacies in Wayne County between 2007 and 2012.

67. Defendant, McKESSON CORPORATION, sold more than 1.2 million doses to pharmacies in Wayne County between 2007 and 2012.

68. Defendant, CARDINAL HEALTH, INC., sold more than 1 million doses to pharmacies in Wayne County between 2007 and 2012.

69. Defendant, SAJ DISTRIBUTORS, sold more than 960,000 doses to pharmacies in Wayne County between 2007 and 2012.

70. Defendant, WAL-MART STORES EAST, LP, sold more than 1 million doses to pharmacies in Wayne County between 2007 and 2012.

71. Defendant, AMERISOURCEBERGEN DRUG CORPORATION, sold more than 660,000 doses to pharmacies in Wayne County between 2007 and 2009.

72. Defendant, TOP RX, LLC, sold more than 430,000 doses to pharmacies in Wayne County between 2007 and 2012.

73. Collectively, the Defendant Wholesale Distributors sold over **8 million doses** of prescription opioids to retailers in Wayne County which has a population of **42,481** according to the 2010 U.S Census report. To put this in perspective, the United States consumes opioid pain relievers (OPR) at a greater rate than any other nation. West Virginia has an OPR prescription rate of 137.6 per 100 persons which ranks 3rd in the country (U.S. average rate: 82.5) and a benzodiazepine prescription rate of 71.9 per 100 persons which ranks 1st nationally (U.S. average rate: 37.6).[3] *See* Leonard J. Paulozzi, MD et al., *Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines – United States, 2012*, Morbidity and

[3] The combination of hydrocodone, oxycodone, and benzodiazepines is referred to as the "holy trinity" and significantly increases the risk of harm to those that abuse prescription pills.

Mortality Weekly Report, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (July 4, 2014) attached hereto as Exhibit 7.

74. The sheer volume of prescription opioids distributed to pharmacies in Wayne County is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them. *Masters Pharmaceuticals, Inc.; Decision and Order*, 80 FR 55418-01, 55482.

75. Plaintiff, WAYNE COUNTY COMMISSION, is of the information and belief that the Defendant Wholesale Distributors failed to report any "suspicious orders" originating from Wayne County to the DEA and/or the West Virginia Board of Pharmacy between 2007 and 2012.

76. Plaintiff, WAYNE COUNTY COMMISSION, alleges that the Defendant Wholesale Distributors unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Wayne County.

77. 21 U.S.C.A. § 823(b)(1), 21 CFR 1301.74(b), 15 CSR 2-4.2.1 and 15 CSR 2-4.4 are public safety statutes.

78. Defendant Wholesale Distributors breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels in violation of 21 U.S.C.A. § 823(b)(1).

79. Defendant Wholesale Distributors breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the DEA of "suspicious orders when discovered" in violation of 21 CFR 1301.74(b).

80. Defendant Wholesale Distributors breached their duty to provide effective controls and procedures to guard against theft and diversion of controlled substances in violation of 15 CSR 2-4.2.1.

81. Defendant Wholesale Distributors breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the West Virginia Board of Pharmacy of suspicious orders when discovered" in violation of 15 CSR 2-4.4.

82. Defendant Wholesale Distributors' violations of public safety statutes constitute prima facie evidence of negligence under West Virginia law.

83. Defendant Wholesale Distributors breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into other legitimate medical, scientific and industrial channels. *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

84. **Defendant Wholesale Distributors breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from Wayne County, West Virginia.**

85. The unlawful conduct by the Defendant Wholesale Distributors is purposeful and intentional. Bluntly, they refuse to abide by the duties imposed by law which are required to maintain a DEA registration to distribute prescription opiates.

86. Defendant Wholesale Distributors refuse to recognize any duty beyond *reporting* suspicious orders. In *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, 2016 WL 1321983 (C.A.D.C.) (April 4, 2016), the Healthcare Distribution Management Association

and National Association of Chain Drug Stores submitted amicus briefs regarding the legal duty of wholesale distributors under the CSA. They argued**:**

> ■ The "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled. Those added obligations would significantly expand the "report-only" duty of distributors under the longstanding regulatory scheme and impose impractical obligations on distributors, which occupy a fundamentally different position than the physicians who prescribe the drugs to patients or pharmacists who dispense drugs to fill those prescriptions. (emphasis in original) (Exhibit 5, *4);
>
> ■ The "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications." (internal citations omitted) (internal quotes omitted) (emphasis in original) (Exhibit 5, *5);
>
> ■ "Nothing in Sections 1301.72-1301.76 requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious." (Exhibit 5, *8);
>
> ■ "The practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties." (Exhibit 5, *10);
>
> ■ "DEA's regulations [] sensibly impose [] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders." (emphasis in original) (Exhibit 5, *11);
>
> ■ "There is simply no practical way for distributors to look over the shoulder of pharmacists and doublecheck the validity of each prescription in light of an individual patient's circumstances." (Exhibit 5, *11);

- "Imposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands." (Exhibit 5, *12);

- "Given the unique role that distributors occupy in the healthcare system, any attempt to impose additional obligations on them to investigate and halt suspicious orders would raise serious policy and practical issues, such as the disruption of patient access to prescribed medications." (Exhibit 5, *12).

87. It should be noted that oral argument was held on January 12, 2017, before the Court of Appeals for the DC Circuit. The positions taken by the trade groups is emblematic of the position taken by the Defendant Wholesale Distributors regarding its duties under the CSA. *See* Amicus Curiae Brief of HDMA, *Cardinal Health, Inc. v. United States Dept. Justice*, Exhibit 6 (arguing the wholesale distributor industry "does not know the rules of the road" because they claim the "DEA has not adequately explained them.").

88. "Ignorance of the law excuses no one." *State v. Ross*, 70 W. Va. 549, 74 S.E. 670, 674 (1912).

89. As a result of the decade-long refusal by the Defendant Wholesale Distributors to abide by federal law, the DEA has repeatedly taken administrative action to force compliance. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 177 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders. *The Drug Enforcement Administration's Adjudication of Registrant Actions*, United States

Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003 (May 2014). The public record reveals many of these actions:

(a) On April 24, 2007, the DEA issued *an Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement which resulted in the suspension of its DEA registration;

(b) On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

(c) On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

(d) On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

(e) On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

(f) On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 CFR § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

(g) On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia

("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

(h) On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

(i) On June 11, 2013, Walgreens paid $80 million in civil penalties for dispensing violations under the CSA regarding the Walgreens Jupiter Distribution Center and six Walgreens retail pharmacies in Florida;

(j) On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

(k) On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

90. Rather, than abide by these public safety statutes, the Defendant Wholesale Distributors, individually and collectively through trade groups in the industry, pressured the U.S. Dept. of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued. *See* Lenny Bernstein and Scott Higham, *Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control*, THE WASHINGTON POST (October 22, 2016); Lenny Bernstein and Scott Higham, *Investigation: U.S. senator calls*

for investigation of DEA enforcement slowdown amid opioid crisis, THE WASHINGTON POST (March 6, 2017); Eric Eyre, *DEA agent: 'We had no leadership' in WV amid flood of pain pills*, Charleston Gazette (February 18, 2017).

91. Meanwhile, the opioid epidemic rages unabated in Wayne County, West Virginia.

92. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the wholesale distributor industry. They pay fines as a cost of doing business in an industry which generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility. And, as bluntly noted by Cardinal Health in its pleadings in *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012), "suspension … will not address the harm DEA alleges because it will not prevent pharmacies filling illegitimate prescriptions from simply obtaining controlled substances from another distributor."

93. Defendant Wholesale Distributors have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement in West Virginia and abused the privilege of distributing controlled substances in our community.

94. The repeated filling of suspicious orders, over an extended period of time, in violation of public safety statutes by the Defendant Wholesale Distributors demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages. *Manor Care, Inc. v. Douglas*, 234 W. Va. 57, 763 S.E.2d 73, Syl. Pt. 5 (2014).

CAUSATION

95. Defendant Wholesale Distributors' failure to monitor, detect, investigate, refuse and report suspicious orders is a direct and proximate ***cause*** of the diversion of millions of prescription opiates into the illicit market for nonmedical purposes in Wayne County, West Virginia.

96. The unlawful conduct by Defendant Wholesale Distributors ***caused*** the very harm the federal and state laws were intended to prevent; namely, the diversion of prescription opiates for nonmedical purposes.

97. The unlawful diversion of prescription opiates is a direct and proximate ***cause*** of prescription opiate abuse, addiction, morbidity and mortality in Wayne County, West Virginia.

98. The unlawful diversion of prescription opiates is a direct and proximate ***cause*** of the prescription opiate epidemic currently plaguing Wayne County, West Virginia.

99. The unlawful diversion of prescription opiates is a direct and proximate ***cause*** of the heroin epidemic currently plaguing Wayne County, West Virginia.

100. The CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are 40x more likely to be addicted to heroin. *See* CDC Vital Signs Fact Sheet, *Today's Heroin Epidemic*, U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention (July 2015) attached as Exhibit 8.

101. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids nonmedically before they initiated

heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. *See* Wilson M. Compton, MPE, *Relationship between Nonmedical Prescription Opioid Use and Heroin Use*, NEW ENG. J. MED., 374:154-63 (January 14, 2016) attached as Exhibit 9.

102. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. ***Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use,*** specifically among persons who report past-year dependence or abuse. The increased availability of heroin, combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose. *See* Rose A. Rudd, MSPH, et al., *Increases in Drug and Opioid Overdose Deaths — United States, 2000–2014*, Morbidity and Mortality Weekly Report (MMWR), Centers for Disease Control and Prevention, 64(50);1378-82 (January 1, 2016) attached as Exhibit 10.

103. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions**.** *See* Nora D. Volkow, M.D., and A. Thomas McLellan, Ph.D., *Opioid Abuse in Chronic Pain*, NEW ENG. J. MED., 374:1253-63 (March 31, 2016) attached as Exhibit 11.

104. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications." *See* Special Report, FDA Commissioner Robert M. Califf,

M.D., *A Proactive Response to Prescription Opioid Abuse*, NEW ENGL. J. MED., 374;1480-85 (April 14, 2016) attached as Exhibit 12.

105. The increased use of prescription painkillers for nonmedical reasons (without a prescription for the high they cause), along with growing sales, has contributed to a large number of overdoses and deaths. *See* Press Release, *Prescription painkiller overdoses at epidemic levels*, U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention (November 1, 2011) attached as Exhibit 13.

106. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes." *See* Richard C. Dart, MD, et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, NEW ENGL. J. MED., 372:241-248 (January 15, 2015) attached as Exhibit 14.

107. The public health dangers associated with the diversion and abuse of controlled prescription drugs have been well-recognized over the years by Congress, DEA, HDMA and NACDS and its members, and public health authorities. *See* Brief for HDMA and NACDS, *4, *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, Exhibit 5; Amicus Curiae Brief of HDMA, *2-3, *Cardinal Health, Inc. v. United States Dept. Justice*, Exhibit 6.

DAMAGES

108. Whatever the measure, the past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United

States. *See* Dart, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, Exhibit 14.

109. Prescription opioids became widely available in the mid-1990s. Between 1997 and 2007, per capita purchases of methadone, hydrocodone and oxycodone increased 13-fold, 4-fold, and 9-fold respectively. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month. *See* Katherine M. Keyes, Ph.D., et al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, AMER. J. PUB. HEALTH, Vol. 104, No.2, e52-e59 (February 2014) attached as Exhibit 15.

110. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels. The News Release noted:

> ■ The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
>
> ■ More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
>
> ■ Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
>
> ■ The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers nonmedically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.

> ■ Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.
>
> ■ Almost 5,500 people start to misuse prescription painkillers every day.

See CDC Press Release, *Prescription painkiller overdoses at epidemic levels*, Exhibit 13.

111. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population. *See* Califf, *A Proactive Response to Prescription Opioid Abuse*, Exhibit 12.

112. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2014 there were almost 19,000 overdose deaths in the United States associated with prescription opioids. *See* Califf, *A Proactive Response to Prescription Opioid Abuse*, Exhibit 12.

113. The former President of the United States declared an opioid and heroin epidemic. *See* Barack Obama, President of the United States, Proclamation 9499, *Prescription Opioid and Heroin Epidemic Awareness Week*, 2016, 81 FR 65173 (September 16, 2016) attached as Exhibit 16.

114. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid. *See* Rose A. Rudd, MSPH, et al., *Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015*, Morbidity and Mortality Weekly Report (MMWR), Centers for Disease Control and Prevention, 65(50-51);1445–1452 (December 30, 2016) attached hereto as Exhibit 17.

115. Fundamentally, prescription opioids and heroin are elements of a larger epidemic of opioid-related disorders and death. Viewing them from a unified perspective is essential to improving public health. The perniciousness of this epidemic requires a multipronged interventional approach that engages all sectors of society. *See* Compton, *Relationship between Nonmedical Prescription Opioid Use and Heroin Use*, Exhibit 9.

116. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years. *See* Volkow, *Opioid Abuse in Chronic Pain*, Exhibit 11.

117. West Virginia has the highest rate of drug overdose deaths in the United States. West Virginia had 36.3 drug overdose deaths per 100,000 people in 2011, nearly triple the U.S. rate (13.2/100,000). Prescription drugs – opioids and benzodiazepines in particular – are major drivers of the drug overdose deaths in West Virginia. Opioid-prescribing rates in West Virginia are among the highest in the country. In 2012, West Virginia providers wrote 137.6 opioid pain reliever prescriptions per 100 people, the third highest prescribing rate in the country and far above the U.S. rate (82.5/100). *See* Press Release, Centers for Disease Control and Prevention, "*CDC awards over $1 Million to West Virginia to address prescription drug overdose prevention*" (August 14, 2014) attached as Exhibit 18.

118. In 2014, West Virginia had the highest drug overdose death rate in the United States (35.5 deaths per 100,000 people). In 2015, West Virginia again had the highest drug overdose death rate in the United States (41.5 deaths per 100,000 people).

119. The opioid epidemic has ravaged West Virginia. *See* Correspondence from James L. Madara, M.D., Executive Vice President, CEO, American Medical Association, to WVAG Patrick Morrisey (August 2, 2016) attached as Exhibit 19.

120. The epidemic of opioid abuse is plaguing our state. *See* Correspondence from Paula Taylor, RPh, M.D., President West Virginia State Medical Association to WVAG Patrick Morrisey (August 9, 2016) attached as Exhibit 19.

121. For over a decade, our state has been at the top, if not led the nation, in prescription drug overdose deaths. *See* Correspondence from Robert C. Knittle, Executive Director, State of West Virginia Board of Medicine to WVAG Patrick Morrisey (August 9, 2016) attached as Exhibit 19.

122. West Virginia leads the nation in opioid deaths and has a drug addiction problem that is devastating families and communities across the state. *See* Correspondence from Louise Reese, CEO WV Primary Care Association to WVAG Patrick Morrisey (August 9, 2016) attached as Exhibit 19.

123. This unfolding public health crisis has profoundly affected individuals, families, and communities throughout our country. *See* Califf, *A Proactive Response to Prescription Opioid Abuse*, Exhibit 12.

124. The illegal importation, manufacture, distribution, possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people. 21 U.S.C.A. § 801(2).

125. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country. *See* Presidential Memorandum – Addressing

Prescription Drug Abuse and Heroin Use, The White House, Office of the Press Secretary (October 21, 2015) attached as Exhibit 20.

126. The societal costs of prescription drug abuse are "huge." *See* Amicus Curiae Brief of HDMA, *6, *Cardinal Health, Inc. v. United States Dept. Justice*, Exhibit 6.

127. Wayne County is one of several southern West Virginia counties on the frontline of the prescription opiate and heroin epidemic. According to data drawn from Vital Statistics from the National Center for Health Statistics (NCHS), in 2014 the United States experienced a drug poisoning death rate of 14.8 (per 100,000 population), West Virginia experienced a drug poisoning rate of 34.7 (per 100,000 population) and **Wayne County experienced a drug poisoning rate of 43.8 (per 100,000 population). The drug poisoning death rate in Wayne County has consistently exceeded the national average during the prescription opiate epidemic:**

3.22x the national average in 2010
3.24x the national average in 2011
2.18x the national average in 2012
3.12x the national average in 2013
2.97x the national average in 2014

128. Prescription opiate abuse, addiction, morbidity, and mortality are hazards to public health and safety in Wayne County, West Virginia.

129. Prescription opiate abuse, addiction, morbidity, and mortality are a temporary public nuisance in Wayne County, West Virginia, which remains unabated.

130. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in Wayne County, West Virginia.

131. Heroin abuse, addiction, morbidity, and mortality are a temporary public nuisance in Wayne County, West Virginia, which remains unabated.

132. A county commission only has powers expressly conferred by the West Virginia Constitution and our State Legislature, or powers reasonably and necessarily implied for the exercise of those expressed powers. *Berkeley Cty. Comm'n v. Shiley*, 170 W. Va. 684, 685–86, 295 S.E.2d 924, 926 (1982) (citing *State ex rel. County Court of Cabell County v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34, Syl. Pt. 1 [1965]). The WAYNE COUNTY COMMISSION is vested with the power of all superintendence and administration of the internal police and fiscal affairs of Wayne County. W. Va. Code § 7-1-3 [1999].

133. The WAYNE COUNTY COMMISSION is "authorized to enact ordinances, issue orders and take other appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-3kk [2002].

134. The unlawful conduct by the Defendant Wholesale Distributors has created hazards to public health and safety and a temporary public nuisance in Wayne County, West Virginia, which remains unabated.

135. Plaintiff, WAYNE COUNTY COMMISSION, seeks economic damages from the Defendant Wholesale Distributors as reimbursement for the costs association with past efforts to eliminate the hazards to public health and safety.

136. Plaintiff, WAYNE COUNTY COMMISSION, seeks economic damages from the Defendant Wholesale Distributors to pay for the cost to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

137. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed." *See* Rudd, *Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015*, Exhibit 17.

138. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain. *See* Alexander GC, Frattaroli S, Gielen AC, eds. *The Prescription Opioid Epidemic: An Evidence-Based Approach*, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland: 2015 attached as Exhibit 21.

139. These community-based problems require community-based solutions which have been limited by "budgetary constraints at the state and Federal levels." *See* Barack Obama, President of the United States, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011) attached as Exhibit 22.

140. Plaintiff, WAYNE COUNTY COMMISSION, seeks to eliminate such budgetary constraints by holding the Defendant Wholesale Distributors financially responsible for the economic costs of eliminating the hazards to public health and safety and abating the temporary public nuisance caused by the unlawful conduct recited herein.

141. Plaintiff, WAYNE COUNTY COMMISSION, seeks non-economic damages from the Defendant Wholesale Distributors as just compensation for annoyance, discomfort, and inconvenience caused by the temporary public nuisance. *Taylor v. Culloden Pub. Serv. Dist.*, 214 W. Va. 639, 591 S.E.2d 197, Syl. Pt. 3 (2003).

142. Plaintiff, WAYNE COUNTY COMMISSION, seeks punitive damages to deter the Defendant Wholesale Distributors and others from committing like offenses in the future. *Hensley v. Erie Ins. Co.*, 168 W. Va. 172, 183, 283 S.E.2d 227, 233 (1981).

143. Plaintiff, WAYNE COUNTY COMMISSION, contends it continues to suffer harm from the negligent and/or unlawful actions by the Defendant Wholesale Distributors.

144. The continued tortious conduct by the Defendant Wholesale Distributors causes a repeated or continuous injury. The damages have not occurred all at once but have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing has not ceased. The public nuisance remains unabated. *Rhodes v. E.I. du Pont de Nemours & Co.*, 657 F. Supp. 2d 751, 760 (S.D.W. Va. 2009), *aff'd in part, appeal dismissed in part,* 636 F.3d 88 (4th Cir. 2011).

145. Plaintiff, WAYNE COUNTY COMMISSION, alleges it is unreasonable for the Defendant Wholesale Distributors to engage in the conduct described herein without paying for the harm done. Although a general activity may have great utility, it may still be unreasonable to inflict the harm without compensating for it. Restatement (Second) of Torts § 821B, comment i (1979).

146. Redress of the wrong to the entire community is left to its duly appointed representatives. Restatement (Second) of Torts § 821C (1979).

147. Plaintiff, WAYNE COUNTY COMMISSION, seeks compensatory and punitive damages from the Defendant Wholesale Distributors for the creation of a public nuisance. *State ex rel. Smith v. Kermit Lumber & Pressure Treating Co.*, 200 W. Va. 221, 241, 488 S.E.2d 901, 921 (1997).

CONCLUSION

148. The WAYNE COUNTY COMMISSION is well aware that some diversion occurs at each level of the chain of distribution of prescription opiates. Any effective strategy to combat the opioid epidemic, however, must address the problems at the distribution and supplier levels.

149. The opioid epidemic still rages in Wayne County. Like others in the chain of distribution, wholesale distributors should face the consequences for breaking the law and be held responsible for the damages they have caused.

150. Congress specifically designed the closed system of distribution to prevent the widespread diversion of prescription opiates. Defendant Wholesale Distributors opened Pandora’s Box and released a seemingly endless supply of prescription opiates into Wayne County and fed the epidemic while making billions of dollars.

151. The WAYNE COUNTY COMMISSION is the proper public official to vindicate the rights of the public, eliminate the hazards to public health and safety and abate the opioid epidemic.

152. The privilege of holding a wholesale distributor license comes with the duty to abide by federal and state safety laws designed to monitor, detect and prevent the diversion of controlled substances. Plaintiff, WAYNE COUNTY COMMISSION, alleges the Defendant Wholesale Distributors unlawfully and negligently breached their duty which is a proximate cause of the opioid epidemic plaguing Wayne County. The unlawful and negligent conduct by the Defendant Wholesale Distributors has created a hazard to public health and safety in Wayne County and constitutes a public nuisance under West Virginia law. Plaintiff, WAYNE

COUNTY COMMISSION, brings this civil action pursuant to its authority to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-3kk [2002].

WHEREFORE, Plaintiff, WAYNE COUNTY COMMISSION, demands economic, noneconomic, and punitive damages from the Defendant Wholesale Distributors including such sums as necessary to eliminate the hazard to public health and safety and to abate, or cause to be abated, the public nuisance caused by the opioid epidemic, as well as any other damages as may be available under West Virginia law.

PLAINTIFF DEMANDS A TRIAL BY JURY.

WAYNE COUNTY COMMISSION
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